Stereotactic Radiotherapy for Metastasis to the Lung

Published: 12-11-2008
Last updated: 06-05-2024

To determine whether SRT achieves a local control rate comparable to surgery in patients with metastatic lung disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON35375

Source
ToetsingOnline

Brief title
Stereotactic Radiotherapy for Metastasis to the Lung

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms
- Respiratory tract therapeutic procedures

Synonym
lung cancer, lung malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lung, Metastasis, Radiotherapy, Stereotactic

Outcome measures

Primary outcome

Local control

Secondary outcome

To determine whether treatment related toxicity is acceptable (maximal toxicity

grade I-III).

To determine prognostic factors on local control, overall survival and

progression free survival.

Study description

Background summary

Local treatment of metastases limited to a few sites could prolong life and potentially be curable. Five-year overall survival rates of 33-58% have been reported in patients with limited metastases. Although surgery is the treatment modality of choice, few patients are suitable candidates due to comorbid disease or insufficient pulmonary reserve. For these patients stereotactic body radiation therapy (SRT) may prove beneficial.
SRT is widely used for treatment of early-stage NSCLC and is currently carefully extended to patients with oligometastases. Okunieff achieved a local control of 91% after 3 years in patients with a maximum of 5 metastatic lesions and disease limited to the thorax. No grade 4-5 toxicity was reported in this series of 125 treated metastatic lesions. Although these results are promising, experience with SRT in patients with oligometastases is still limited and further investigation is warranted.

Study objective

To determine whether SRT achieves a local control rate comparable to surgery in patients with metastatic lung disease.

Study design

Non-randomized, single center prospective phase II trail

Intervention

Patients will be treated with 3-7 fractions of stereotactic radiotherapy depending on the tumor location. Prior to treatment fiducials will be placed using one of the following methods: bronchoscopy, percutaneous intra- or extra-pulmonary placement or intravascular placement. These fiducials are required for the cyberknife to *track* the tumor, enabling a high radiation dose to be delivered to a limited lung volume.

Study burden and risks

The sole invasive procedures in the study are the placement of fiducials and the administration of intravenous contrast for CT-scan imaging. The risk for complications is greatest after percutaneous intrapulmonal fiducial placement, reporting a 10-28% incidence of pneumothorax. This risk will be minimized by careful patient selection for one of the three fiducial placement techniques. During the study duration of maximum three years, a total of 12 visits to the outpatient clinic are planned. In addition to the imaging required for treatment planning, during the follow up an extra CT-scan is planned at nine months for treatment evaluation. Exposure to radiation from this diagnostic imaging is low compared to treatment dose delivered.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 5201
3008 AE Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 5201
3008 AE Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The patient is eighteen years or older.
The metastases are limited to a maximum of 2 organs, and one of the 2 is the lung.
The patient has no more than 5 metastatic lesions.
The primary tumor site is locally controlled.
The interval between treatment of the primary tumor and diagnosis of the metastasis is at least four months.
The patient has a life expectancy of at least 6 months.

Exclusion criteria

Patients with more than 5 metastatic lesions.
Patients with an active primary tumor site.
pregnant women.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2008
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-07-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL23450.078.08